DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: TYZEKA
Patent Nos: 6,395,716 and 6,569,837
Docket Nos.: 2007E-0133 and 2007E-0148

MAY 6 2008

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent Nos. 6,395,716, and 6,569,837, filed by Idenix Pharmaceuticals, Inc., Centre National de La Recherche Scientifique, and L'Universite Montpellier II, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for TYZEKA (telbivudine), the human drug product claimed by the patents.

The total length of the regulatory review period for TYZEKA (telbivudine) is 2,309 days. Of this time, 2,009 days occurred during the testing phase and 300 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 1, 2000.

   The applicant claims the investigational new drug application (IND) was under clinical hold until August 15, 2000, and claims that date as the date the IND became effective. However, according to FDA records, the IND was considered safe to proceed with some recommendations that were sent to the sponsor to consider prior to commencement of the study. The IND effective date was July 1, 2000, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 30, 2005.

   FDA has verified the applicant's claim that the new drug application (NDA) for TYZEKA (telbivudine) (NDA 22-011) was initially submitted on December 30, 2005.

3. The date the application was approved: October 25, 2006.

FDA has verified the applicant's claim that NDA 22-011 was approved on October 25, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: James D. Johnson, Ph.D.
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